Subject: RE: statement from UC San Diego
From: "Carr, Jacqueline" <jcarr@ucsd.edu>
Date: 4/11/19, 7:39 AM
To: Brad Racino <bradracino@inewsource.org>
CC: "Lafee, Scott" <slafee@ucsd.edu>

Thank you. Yes, Friday is reasonable. Below is the first set of responses. I will answer your other email shortly. Best, Jackie

Q: Thank you for this, but do you mean prohibited from serving as PI on any clinical trial IRB protocol? Or any protocol at all? Because he's listed as the PI in a 2018 UCSD study "MOLECULAR MECHANISM AND THERAPY FOR OCULAR MELANOMA" on the NIH Reporter website. And was the suspension implemented immediately following the audit report?

A: Dr. Zhang is prohibited from being a PI on all IRB protocols. However, he is still permitted to apply for research grants, which is a separate process. The PI on a grant has fiscal, scientific and organizational responsibility for a study. In this case, Dr. Zhang is currently the PI on the grant that you reference but he is not the PI of the IRB protocol. The PI on an IRB protocol has specific oversight of all human subjects related activity, including identifying potential participants, obtaining consent, performing the study, reporting adverse events, tracking study accrual and reporting results. Dr. Zhang is not permitted to supervise the IRB-approved activities and those have been assigned to another UC San Diego faculty member. His suspension from protocols began April 2017.

Q: Though I do have one more question that's more of a process/procedure one I forgot to ask: UCSD's HRPP website says it is responsible "for review of research involving human subjects conducted by all Schools, Centers, and Programs of UCSD" and "oversees the review and conduct of research conducted by federally registered Institutional Review Boards (IRBs)." But does that mean reviewing only the protocols? Or are there ongoing compliance checks, enrollment record reviews, etc.? Same goes for the IRB. Does it ever do any compliance checks along the way, or does it rely solely on updates and progress reports from a researcher such as Dr. Zhang?

A: The IRB Office does not have an audit function. It reviews protocols, evaluates risks and benefits of studies, and assesses all components of a research study to determine if it is appropriate, well designed, considers impact on vulnerable populations, and protects confidentiality of data. The IRB has requirements for the protocol PI such as identifying and reporting adverse events and providing regular reports for annual protocol renewal. Research Compliance performs regular audits, reviews documentation such as consent and case report forms, and reviews overall study compliance. Separation of IRB review and auditing function is essential and assures that the compliance assessments are independent.

Jacqueline Carr
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UC San Diego Health Sciences
cell: 858-344-3799

From: Brad Racino [bradracino@inewsource.org]
Sent: Wednesday, April 10, 2019 6:14 PM
To: Carr, Jacqueline
Cc: Lafee, Scott
Subject: Re: statement from UC San Diego

Jackie,

Thank you for this, but do you mean prohibited from serving as PI on any *clinical trial* IRB protocol? Or any protocol at all? Because he's listed as the PI in a 2018 UCSD study "MOLECULAR MECHANISM AND THERAPY FOR OCULAR MELANOMA" on the NIH Reporter website. And was the suspension implemented immediately following the audit report?

We are planning to run this next week and would like to have things wrapped up by end of day Friday, if you think that's reasonable.

Though I do have one more question that's more of a process/procedure one I forgot to ask: UCSD's HRPP website says it is responsible "for review of research involving human subjects conducted by all Schools, Centers, and Programs of UCSD" and "oversees the review and conduct of research conducted by federally registered Institutional Review Boards (IRBs)." But does that mean reviewing only the protocols? Or are there ongoing compliance checks, enrollment record reviews, etc.? Same goes for the IRB. Does it ever do any compliance checks along the way, or does it rely solely on updates and progress reports from a researcher such as Dr. Zhang?

Carr, Jacqueline April 10, 2019 at 6:05 PM

Hi Brad- To your first question, Dr. Zhang is prohibited from serving as PI on any IRB protocol at UC San Diego indefinitely.

I have inquiries out about questions 2-4.

What is the latest you can hear from us before you publish?

Best, Jackie

Jacqueline Carr
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UC San Diego Health Sciences
cell: 858-344-3799

From: Brad Racino [bradracino@inewsource.org]
Sent: Wednesday, April 10, 2019 11:40 AM
To: Carr, Jacqueline
Cc: Lafee, Scott
Subject: Re: statement from UC San Diego

Thank you Jackie. I'm hoping you can answer some follow-up questions as soon as

possible.

1. How long was Dr. Zhang's suspension? Or is it still ongoing? And why only clinical trials opposed to any research involving human subjects?
2. Did UCSD alert any oversight agencies, such as the NIH, FDA, OHRP, ORI, or California Medical Board to its audit findings?
3. In the same vein, did UCSD alert any institutions where Zhang conducts research, including the San Diego VA?
4. The audit examined Zhang's current research. Did UCSD look at any other previous research he had done? If not, please explain the reasoning, considering its finding violations in 100 percent of the studies that involved enrolled human subjects.

I appreciate the help.

-Brad

Brad Racino April 10, 2019 at 11:40 AM

Thank you Jackie. I'm hoping you can answer some follow-up questions as soon as possible.

1. How long was Dr. Zhang's suspension? Or is it still ongoing? And why only clinical trials opposed to any research involving human subjects?
2. Did UCSD alert any oversight agencies, such as the NIH, FDA, OHRP, ORI, or California Medical Board to its audit findings?
3. In the same vein, did UCSD alert any institutions where Zhang conducts research, including the San Diego VA?
4. The audit examined Zhang's current research. Did UCSD look at any other previous research he had done? If not, please explain the reasoning, considering its finding violations in 100 percent of the studies that involved enrolled human subjects.

I appreciate the help.

-Brad

Carr, Jacqueline April 10, 2019 at 10:57 AM

Hi Brad- Thank you for your patience in waiting for a response. Here is the statement from UC San Diego related to Dr. Kang Zhang:

MEDIA STATEMENT
As a result of the 2017 FDA warning letter and subsequent UCSD Ophthalmology

Human Subjects Research Compliance report you referenced, UC San Diego implemented a comprehensive management action plan to address these issues, including document corrections, retraining key personnel, requiring a secondary screening process, and suspending Dr. Kang Zhang from serving as principal investigator (PI) on any protocols.

Best, Jackie

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Good afternoon Jackie,

In the course of researching the human research study done at the San Diego VA, we came across a UC audit and FDA warning letter specific to Dr. Kang Zhang, who is the Chief of Ophthalmic Genetics and a Professor of Ophthalmology at UCSD.

The audit and warning letter found a number of problems with several of Zhang's studies. We have passed the findings along to several experts for their review, and so far all have said the major findings are troubling and appear to show a pattern.

We would like to interview Dr. Zhang and/or Robert Weinreb – the chair of the Shiley Eye Institute where Dr. Zhang works – about the audit and letter, any corrective actions taken and steps to ensure future compliance.

Please let me know if you can help arrange that interview, and/or provide any additional context, findings, reviews or relevant documents related to Dr. Zhang's research.

Thank you for your help.

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Check out our 2018 annual report to see our most impactful stories, behind-the-scenes footage, and more!

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